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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,713	07/01/2003	David A. Tirrell	110197.402C1	3724
500	7590	09/11/2006	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			GUZO, DAVID	
701 FIFTH AVE			ART UNIT	
SUITE 6300			PAPER NUMBER	
SEATTLE, WA 98104-7092			1636	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/612,713	<b>Applicant(s)</b> TIRRELL ET AL.	
	<b>Examiner</b> David Guzo	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-12,14,17-22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-12,14,17-22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### Detailed Action

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-8, 10-12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,586,207 (hereafter the '207 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method for producing a modified polypeptide of interest wherein an amino acid analog is incorporated into the polypeptide through over-expression of an aminoacyl-tRNA synthetase. The instant claims differ from those of the '207 patent in that the instant claims recite a transforming a host cell with a sequence encoding an aminoacyl-tRNA synthetase for the amino acid analogue while the claims in the '207 patent recite an aminoacyl-tRNA synthetase for the selected amino acid. The claims

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are not patentably distinct however, because aminoacyl-tRNA synthetases can recognize naturally occurring amino acids **and** amino acid analogues and hence both sets of claims can read on over-expressing the same synthetase. The claims in the '207 patent would therefore anticipate the claimed invention. This rejection is necessitated by applicants' amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 22 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by RajBhandary.

This rejection is maintained for reasons of record in the previous Office Action (mailed 2/8/06) and for reasons outlined below. The rejection is expanded to include claims 24-25 as a result of applicants' amendment filed 6/8/06.

Applicants traverse this rejection by amending claim 17 to recite an aminoacyl-tRNA synthetase for a desired amino acid analogue and then arguing that the RajBhandary reference does not teach a vector encoding an aminoacyl-tRNA synthetase for a desired amino acid analogue. Applicants assert that RajBhandary only teaches alternative initiator codons and teaches using the 19 naturally occurring amino acids (other than methionine) as an alternative codon.

Applicant's arguments filed 6/8/06 have been fully considered but they are not persuasive. It is well known that aminoacyl-tRNA synthetases can recognize naturally occurring amino acids **and** amino acid analogues (see for example Kiick et al., Tetrahedron, 2000, Vol. 56, pp. 9487-9493) and hence the aminoacyl-tRNA synthetases recited in the RajBhandary reference and in the instant claims can read on the same enzyme. With regard to new claim 24, RajBhandary recites that the host cell is *E. coli*. With regard to claim 25, RajBhandary recites that two vectors can be used with one encoding the aminoacyl-tRNA synthetase and another encoding a protein of interest (such as CAT, see columns 1-2, Figs. 1A-1B, etc.). Therefore RajBhandary teaches the claimed invention. It is noted that secondary evidence can be used, in a 35 USC 102 rejection, to show that a characteristic not recited in an anticipatory reference is inherent (See MPEP 2131.01).

Claims 17-18, 20-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dardel et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include claim 24 as a result of applicants' amendment filed 6/8/06.

Applicants traverse this rejection by amending claim 17 to recite an aminoacyl-tRNA synthetase for a desired amino acid analogue and then arguing that the Dardel et al. reference does not teach a vector encoding an aminoacyl-tRNA synthetase for a desired amino acid analogue.

Applicant's arguments filed 6/8/06 have been fully considered but they are not persuasive. As noted above, it is well known that aminoacyl-tRNA synthetases can recognize naturally occurring amino acids **and** amino acid analogues and hence the aminoacyl-tRNA synthetases recited in the Dardel et al. reference and in the instant claims can read on the same enzyme. With regard to new claim 24, Dardel et al. recites that the host cell is *E. coli* (See Materials and Methods section). Therefore Dardel et al. teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-18, 20-22 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Tao et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include claims 24-25 as a result of applicants' amendment filed 6/8/06.

Applicants traverse this rejection by amending claim 17 to recite an aminoacyl-tRNA synthetase for a desired amino acid analogue and then arguing that the Tao et al.

reference does not teach a vector encoding an aminoacyl-tRNA synthetase for a desired amino acid analogue.

Applicant's arguments filed 6/8/06 have been fully considered but they are not persuasive. As noted above, it is well known that aminoacyl-tRNA synthetases can recognize naturally occurring amino acids **and** amino acid analogues and hence the aminoacyl-tRNA synthetases recited in the Tao et al. reference and in the instant claims can read on the same enzyme. With regard to new claims 24-25, Tao et al. teaches bacterial or yeast cells as the host cells and that two vectors can be used, one comprising the aminoacyl-tRNA synthetase gene and one comprising a sequence encoding a polypeptide of interest (see for example columns 15 and 29). Therefore Tao et al. teaches the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tao et al. in view of Smith et al. or Maddon et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection by amending claim 17 to recite an aminoacyl-tRNA synthetase for a desired amino acid analogue and then arguing that the Tao et al.

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reference does not teach a vector encoding an aminoacyl-tRNA synthetase for a desired amino acid analogue. Applicants argue that the secondary references Smith et al. and Maddon et al.) do not remedy the alleged deficiency of the Tao et al. reference.

Applicant's arguments filed 6/8/06 have been fully considered but they are not persuasive. As noted above, it is well known that aminoacyl-tRNA synthetases can recognize naturally occurring amino acids **and** amino acid analogues and hence the aminoacyl-tRNA synthetases recited in the Tao et al. reference and in the instant claims can read on the same enzyme. Given that the Tao et al. teaches the same synthetase as recited in the instant claims, the Smith et al. and Maddon et al. references are applicable as recited in the previous rejection and render the instant invention obvious.

Any rejection not repeated in this Office Action is withdrawn.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the



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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
August 22, 2006

  
DAVID GUZO  
PRIMARY EXAMINER